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SUBJECT: FRANCE Q SPECIAL 301 2009 ANNUAL REVIEW

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¶1. (SBU) Post has reviewed PhRMA's Special 301 submission on France and recommends against inclusion of France on the 2009 Special 301 Watch List. As we reported in 2008 (refs B and C) GOF efforts to rein in state health insurance spending on pharmaceuticals has made for a challenging environment, particularly for less innovative prescription drugs. But Post sees no deficiencies in IPR protection provided to pharmaceutical products, nor in the provision of fair and equitable market access to pharmaceutical companies.

¶2. (U) Pricing and distribution margins on non-reimbursable pharmaceuticals are unregulated in France. Pharmaceutical companies that do not seek to include their products on the list of drugs to be reimbursed by the state health insurance program can market products immediately upon receipt of market authorization (either via the centralized European procedure or via national procedure).

¶3. (U) The GOF is employing different strategies to limit the cost of its reimbursable drug program, including aggressive use of generics and campaigns to reduce consumption. A September 2008 working paper by the Institut de Recherche et Documentation en Economie de la Sante (IRDES) indicates the nature of the challenge. With 90% of medical consultations resulting in a prescription, and annual per-capita consumption of pharmaceuticals of 500 euros (tops in Europe), France is a high-volume pharmaceutical market.

¶4. (U) Companies wishing to get a drug included on the reimbursable list first approach France's "Transparency Committee." Made up of epidemiologists, pharmacologists, medical doctors and other experts, the Committee assigns an "innovation" rating from ASMR I to ASMR V (I representing a "major therapeutic advance," V "no treatment benefit") based on clinical criteria. Minutes from Commission meetings are posted at http://www.has-sante.fr/portail/jcms/c_692477/commission-de- la-transparence. Once the ASMR rating has been assigned, price negotiations with the Economic Committee for Health Products (CEPS) ensue. Innovative outpatient drugs are considered in an accelerated process, which now are extended to the all drugs up to ASMR III and some low-cost ASMR IV drugs. Maximum delay for setting a price during the registration of a new drug is 180 days. According to IRDES the average was 164 days in 2007.

¶5. (U) In its September 2008 report IRDES noted that

the structure of pharmaceutical sales in France has changed in recent years to favor more expensive products. IRDES concluded that the French, both patients and doctors, "seem to prefer innovative and expensive drugs, even when less expensive ones are as effective, " and that the possibility of higher prices for innovative specialties "makes France an attractive location for the early commercialization of innovative therapies."

¶6. (SBU) Comment: France's national health insurance cost containment efforts do not/not deny adequate and effective IP protection to the U.S. pharmaceutical industry, nor do they prevent fair and equitable market access. Post will continue to support U.S. pharmaceutical industry efforts to expand markets in France, but recommends against France's inclusion on the 2009 Special 301 Watch List.

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